IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK Hon. Robert Kugler

This relates to: All Actions

Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Opinions of Laura Craft

Redacted Version

<u>PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO</u> DEFENDANTS' MOTION TO EXCLUDE OPINIONS OF LAURA CRAFT

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I. <u>INTRODUCTION</u>

Plaintiffs' expert Laura R. Craft, MPH, has almost twenty years of professional experience involving prescription drug pricing, distribution, insurance coverage and reimbursements. Magistrate Judge Schneider and this Court have considered her expert opinions twice before in this matter—once during discovery, and again at class certification. In her third and most recent liability phase declaration, Ms. Craft

"Ex. A (Craft Rpt.) at ¶ 1. She opines on this in the context of a TPP trial involving Plaintiff MSP's two assignors, SummaCare and EmblemHealth, two insurance companies with reimbursements for valsartan-containing drugs ("VCDs") on behalf of thousands of consumers in approximately a dozen different states.

Defendants do not challenge Ms. Craft's formidable credentials to offer her opinions. They do not challenge the reliability or application of her methodology, either. They merely contend her opinions will not assist the jury, or criticize other opinions Defendants themselves elicited with their own deposition questioning but which Ms. Craft does not intend to offer affirmatively in Plaintiffs' case-in-chief. Neither *Daubert* challenge is proper. Thus, Defendants' motion (D.E. 2287) should be denied.

Defendants' assertion that Ms. Craft's opinions are unhelpful (Defs. Mem. at 1, 6-10) rings hollow. Defendants and their experts have repeatedly claimed the drug reimbursement process

. Ms. Craft's concise explanation

. Undoubtedly, her opinions will assist a lay jury in understanding the

The balance of Defendants' *Daubert* motion attacks damages-related opinions about the value of VCDs and the calculation of damages, both of which are topics for which Ms. Craft very clearly articulated were not part of her primary expert report. Rather, as explained at great length, Ms. Craft's declaration focuses on the created for same. She does not purport to quantify damages. Despite the clear delineations between Ms. Craft's expert testimony on the existence of data, and Dr. Conti's expert testimony on the quantification of damages, Defendants spent hours questioning Ms. Craft at her deposition about her views on

Ms. Craft thoughtfully answered these questions (based on her significant expertise in this area) and explained in detail the bases for her disagreement with Mr. Kosty's opinions.

Daubert is not meant to preclude unfavorable answers to a party's own deposition questions. Defendants themselves opened the door to Ms. Craft's views on the credibility and/or reliability of Defendants' own damages-related opinions—views which Ms. Craft is amply qualified to offer by way of rebuttal, and which are sufficiently reliable. They cannot use a Daubert motion to preemptively inhibit Ms. Craft from providing the same answers at trial upon cross examination or in rebuttal.

For these reasons, Defendants' Daubert motion (D.E. 2287) should be denied.

II. APPLICABLE LEGAL STANDARD

"Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted). Rule 702, the rule that governs expert testimony, has a "liberal policy of admissibility." *Id.* In essence, the expert testimony must meet the following requirements: "(1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *Id.* at 244.

A. Qualifications

The qualification requirement of Rule 702 is "liberally construed" and satisfied if an expert "possesses specialized expertise." *Geiss v. Target Corp.*, No. 09-2208, 2013 WL 4675377, at *4 (D.N.J. 2013) (citing *Pineda*, 520 F.3d at 244).

B. Reliability

The second Rule 702 requirement (also known as reliability) is taken to "mean[] that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (citation omitted). While such "good grounds" for an expert's opinion are required, "[t]he grounds for the expert's opinion merely have to be good, they do not have to be perfect." *Id.* at 744. Good grounds may exist even if the court believes there "are better grounds for some alternative conclusion" or that "a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result." *Id.* at 744.

Moreover, proponents of expert testimony do not have to "demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." *In re DVI, Inc. Sec. Litig.*, No. 03-5336, 2014 WL 4634301, at *5 (E.D. Pa. Sep. 16, 2014) (internal quotation marks omitted) (emphasis original); *see also In re Paoli*, 35 F.3d at 744 ("evidentiary requirement of reliability is lower than the merits standard of correctness"). Scientific study is not the only basis for an expert's reliability, which may also be founded upon experience. As the Supreme Court later added in *Kumho Tire*, the objective of *Daubert* "is to make certain that

an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Indeed, the *Daubert* test "may be more flexibly applied in cases where the expert testimony is based on experience." *In re Front Loading Washing Mach. Class Action Litig.*, 2013 WL 3466821, at *2 (D.N.J. July 10, 2013). Moreover, in the case of experience-based opinions, the fact that an expert has been determined to be qualified weighs in favor or the reliability of her report. *Altieri v. State Farm Fire & Cas. Co.*, 2011 WL 1883054, at *3 (E.D. Pa. May 17, 2011).

C. Relevance

The third requirement of Rule 702, known as relevance, is satisfied "if an opinion fits a particular case (and thus helps the trier of fact)" – i.e., there must be a "connection between the scientific research or test result to be presented and particular disputed factual issues in the case." *Geiss v. Target Corp.*, No. 09-2208, 2013 WL 4675377, at *5 (D.N.J. Aug. 30, 2013) (internal quotation marks omitted).

III. BACKGROUND ON MS. CRAFT'S DECLARATION

A. Ms. Craft's Qualifications

Ms. Craft has "

Berkeley. Ex. A (Craft Rpt.). She holds a Master of Public Health (MPH) degree from the University of California, Berkeley. $Id \, \P \, 1$. Her graduate work focused on ." Id. ¶ 4. This included " ." *Id*. Ms. Craft serves as the President of OnPoint Analytics, Inc., " " *Id.* ¶ 5. She has " Id. She has applied her knowledge Ms. Craft also " Id.." *Id*. ¶ 6.

Ms. Craft has "

." Id. ¶ 7. She has analyzed such data twice already in this litigation, and has done so in many other litigations. Id.

Ms. Craft submitted two prior declarations in this litigation. She submitted the first on March 12, 2020 about the types of data and information created and maintained in connection with how prescription drugs travel through the U.S. supply chain. Magistrate Judge Schneider relied in part on this declaration in ordering certain discovery from Retailer and Wholesaler Defendants, demonstrating that her testimony was helpful and assisted him with understanding the drug supply chain, just as it would assist the jury. Ms. Craft's second declaration was submitted in support of class certification on November 10, 2021. Defendants did not file a *Daubert* challenge against Ms. Craft at the class certification stage. This Court relied on Ms. Craft's opinions in granting Plaintiffs' class certification motion. *See* D.E. 2261 at 28, 68.

B. Ms. Craft's Opinions and Methodology

Ms. Craft's assignment was "

Ex. A at ¶ 3.a. To do this, she drew on her significant training and
experience, as well as her review of the
. She first describes how every prescription drug product in the United
States must be labeled at its point of origin with a unique 10- or 11-digit code (known
as the National Drug Code, or "NDC"). <i>Id.</i> ¶ 9. As she opined,
." <i>Id</i> .
She continues to explain how Defendants' NDCs representing their
challenged products "
." <i>Id</i> . ¶ 10.
The "
." <i>id</i> ¶ 11.

IV. ARGUMENT

A. Ms. Craft's Opinions Will Assist the Jury

Defendants have repeatedly contended in this litigation that the flow of payments for prescription drugs is

1 See, e.g., D.E. 2010 (Defs.' Opp'n to TPP Mot. for Class Cert.) at 10 ("

); D.E. 2010-192 (Kosty 1/12/2022 Rpt.) at ¶ 20 ("

"), ¶ 37

) (emphasis original), ¶ 40.f (

; D.E. 2299-3 (Kosty 12/19/2022 Rpt.) at ¶ 44

) (emphasis original).

Court itself observed this in granting class certification.² Lay jurors are not privy to the web of electronic systems and data that operate behind the screen when a consumer receives a prescription drug at a pharmacy dispensing counter. Ms. Craft's testimony will greatly assist the average juror in understanding the systems and data that exist for pharmaceutical transactions; what they show; and how they can be used reliably to calculate SummaCare's and EmblemHealth's (or any other TPP's) damages (which, again, is something Dr. Conti does).

Courts routinely permit expert testimony about industry practices and function. *See, e.g., United States v. Burton*, 404 Fed. Appx. 617, 623 (3d Cir.2010) (expert may testify about illicit drug distribution system); *United States v. Leo*, 941, F.2d 181 (3d Cir. 1991) (expert may testify about defense industry practices). The pharmaceutical drug distribution system is no exception. *See, e.g., United States v. Schiff*, 538 F. Supp. 2d 818, 845-46 (D.N.J. 2008) (expert may opine on "the complex distribution system employed by manufacturers, wholesalers, and retail sellers to provide pharmaceutical products to customers").

Defendants' contention that Ms. Craft's opinions do not bear on "
"(Defs. Mem. at 7) is immaterial. Her opinions go to the existence, nature

² D.E. 2261 (2/8/2023 Op.) at 79-90 (

and veracity of the data available to calculate damages. That Ms. Craft does not perform those calculations herself (*id.* at 8-9) is unavailing. Plaintiffs may use different experts to explain the pharmaceutical drug distribution and payments systems, on the one hand, and to calculate damages on the other.

Ultimately, Ms. Craft reliably applies the facts of this case to distill the purported complexities of the pharmaceutical drug supply chain to understand what data exist and why that data can be used reliably to calculate damages. Such testimony clears the low hurdle of the relevancy/fit/helpfulness prong of Federal Rule of Evidence 702(a). *See* Defs. Mem. at 7 (acknowledging requirement is "not that high"); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

B. Defendants' Remaining Arguments Are Not Proper *Daubert* Challenges

Defendants devote nearly half of their *Daubert* brief to deposition testimony elicited during Defendants' cross examination questioning, including whether Ms.

Craft is qualified to reliably opine on

Defs.' Mem. at 10-

15.

As discussed *supra* Part IV.A, Ms. Craft affirmatively opines

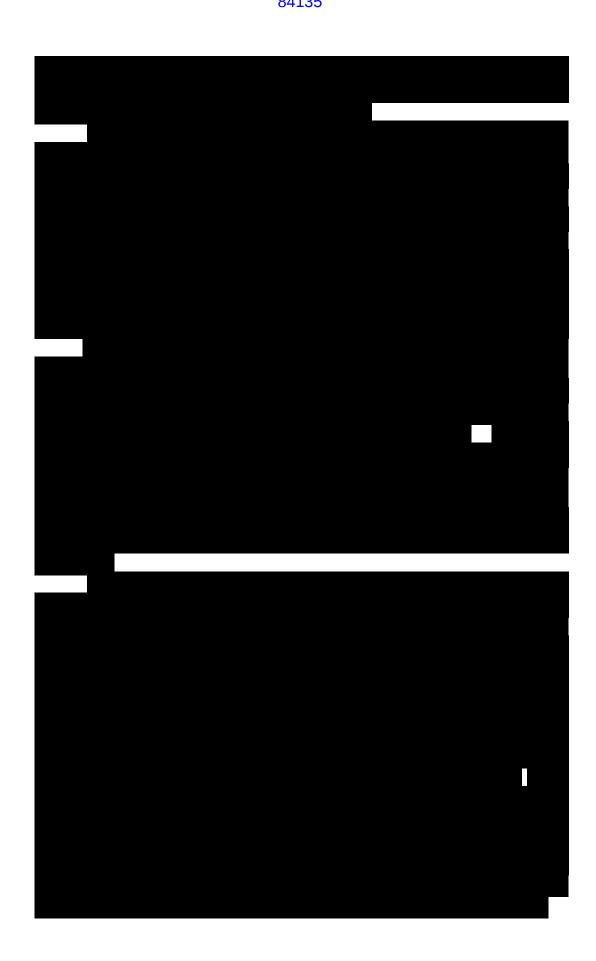
See generally Ex. A. Ms. Craft only offered her views on

. See Defs.
Mem. at 11, 13-14 (only citing Ms. Craft's deposition transcript, not her declaration).
See
Ex. B (Craft 1/12/2023 Tr.) at 99:18-19
. Were Defendants
actually making a legitimate Daubert challenge, they would attempt to argue how or
why this testimony might demonstrate the inherent unreliability of her primary
opinion. But they do no such thing in their motion. Instead, Defendants essentially
seek to prematurely and preemptively move in limine to exclude rebuttal testimony
they simply do not like. This is not an appropriate Daubert challenge.
Ms. Craft cannot be faulted because defense counsel repeatedly probed Ms.
Craft's views on
:
Q:



Ex. B at 86:13 - 88:4. Defense counsel did not stop there. They continued:







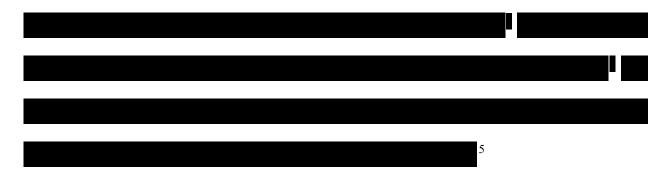
Id. at 88:12 - 94:24. Defense counsel did not quit there. Id. at 94:25 - 98:17.

They continued to press farther:



Id. 98:13 – 100:3.

In short, in response to Defendants' own questions, Ms. Craft explained why



An expert is allowed to contradict or rebut another party's expert. See, e.g.,

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<sup>3</sup> See, e.g., Ex. B at 143:15 – 144:1 (
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<sup>4</sup> Id. at 66:3 – 67:15 ("
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⁵ See, e.g., id. at 86:13 – 100:3.

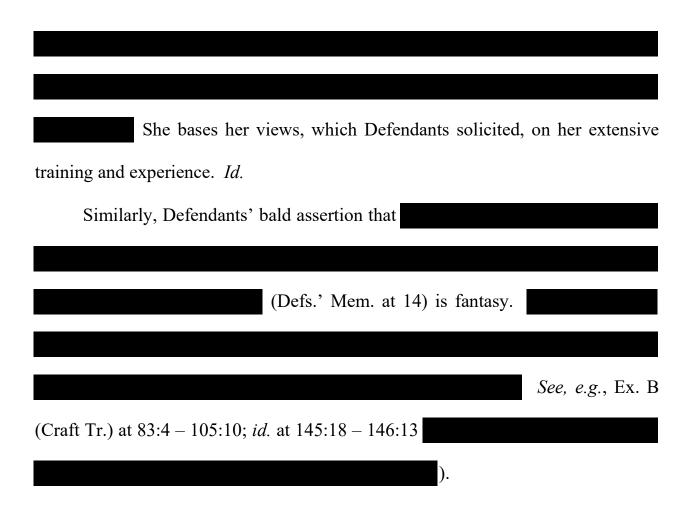
Dzielak v. Whirlpool Corp., No. 2:12-0089, 2017 WL 1034197, at *32 & n.33 (D.N.J. Mar. 17, 2017). Obviously, Ms. Craft could not discuss Mr. Kosty's report (which itself critiqued Ms. Craft's own), because she wrote hers first when his report did not exist yet.

Defendants and their expert Mr. Kosty criticized Ms. Craft's opinions by contending

. When questioned about this at the deposition, Ms. Craft forcibly explained why she disagreed with their criticisms.

Defendants' opening the door to this area at Ms. Craft's deposition does not transmogrify her testimony into new affirmative opinions. *Daubert* is not meant to preclude rebuttal opinions, especially those elicited by a party's own cross-examination. *See, e.g., Oklahoma v. Tyson Foods, Inc.*, No. 05-cv-329, 2009 WL 2252129, at *5 (N.D. Okla. July 24, 2009) (permitting "opinions from previously disclosed expert witnesses that are simply critiques of defendants' expert reports, inasmuch as these opinions may assist the court in evaluating the reliability of the challenged expert's opinion").

Defendants' related attacks on the reliability of Ms. Craft's rebuttal views on fare even worse.



V. **CONCLUSION**

For the foregoing reasons, Defendants' Daubert motion to exclude Ms. Craft's opinions should be denied.

Dated: April 11, 2023 Respectfully,

ON BEHALF OF PLAINTIFFS

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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April 2023, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ David J. Stanoch

David J. Stanoch